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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,650	10/29/2001	Surekha Palreddy	279.399US1	1227

21186 7590 06/24/2004

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER

SCHAETZLE, KENNEDY

ART UNIT PAPER NUMBER

3762

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/046,650	Applicant(s) PALREDDY ET AL.	
	Examiner Kennedy Schaetzle	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
 4a) Of the above claim(s) 16 and 21-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-15 and 17-19 is/are rejected.
- 7) ☒ Claim(s) 7 and 20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/12/02, 2/13/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Claims 16 and 21-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 29, 2004.
2. The examiner wishes to notify the applicant that the subject matter of non-elected claim 16 does not appear to have antecedence in the specification (note the text abridging pages 11 and 12). This issue must be addressed (or clarification given) if a generic claim from which claim 16 depends is subsequently found to be allowable.

Claim Objections

3. Claim 6 is objected to because of the following informalities: the two adjusting phrases in the body of the claim are grammatically awkward (the wrong form of the word "detect" is used). Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-3, 5, 6, 8, 9, 11-15 and 17-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/643,770. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the present invention is in most aspects simply a broader version of claim 1 of the '770 application. The current step of determining whether an evaluation sample of the cardiac signal is a turning point with respect to previous and subsequent samples is merely a broader rephrasing of the determining step in the '770 application. Furthermore, those of ordinary skill in the art would have seen the step of computing a local peak density in a predetermined number of consecutive cardiac samples to obviously include counting the number of peaks, or turning points, over a predetermined plurality of cardiac samples, since peak density is simply a measure of the number of peaks in a given sample period (note also claim 14 of '770). If a patent were to be received based on the '770 application, the applicant would not be entitled to another patent for the generic or broader invention defined by the present claims (see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)).

Regarding claim 6 and similarly worded claims, although the '770 application does not address adjustment of the system to a detection of noise, those of ordinary skill in the art would have seen such a modification of operation as obvious since the whole intent of detecting noise is to counteract the influence that said noise has on the system. The various parameters listed in claim 19 are all well known adjustment parameters when it comes to dealing with noise. The inclusion of any one therefore would have been considered obvious by the ordinarily skilled artisan looking to limit the effect of noise on the system.

Regarding independent claim 13, the specific determining step set forth would have been considered an obvious way of determining a peak value as required in the '770 application. No criticality is given in this method over any other mathematical algorithm for determining peaks or turning points. Clearly a number of known different mathematical techniques (e.g., detection of zero slope values for the curve) may be employed to ascertain the occurrence of a peak.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (Pat. No. 4,589,420).

Regarding claim 1, Adams et al. disclose a method of determining whether a sampled cardiac signal is noisy, including the steps of determining whether an evaluation sample of the cardiac signal is a turning point with respect to previous and subsequent samples (see the text abridging cols. 6 and 7), counting a number of the turning points over a predetermined plurality of cardiac samples, and deeming a window that includes the predetermined plurality of cardiac samples to be noisy if the number of turning points exceeds a threshold value (see col. 7, lines 45-59 and Fig. 7).

Concerning claim 2, note the text abridging cols. 6 and 7 for a specific discussion of determining first and second directions (i.e., slopes) of segments about an evaluation sample, as well as col. 5, lines 46-68 for general background information on slope calculation and turning point detection. By searching for a change in slope (sign) between two successive first differences, Adams et al. are inherently detecting if a first direction is different from a second direction.

Regarding claim 4, since the determination of a turning point (or change in slope sign) requires knowledge of at least three points on a curve in order to calculate the slope prior to a specific point and the slope after a specific point, the frequency of evaluation must inherently be less than the sampling frequency.

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Regarding claim 6, the examiner considers the act of rejecting a candidate beat because of extreme noise conditions within the sample window to constitute at least adjusting the detection of the cardiac signal.

Claim Rejections - 35 USC § 102/103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 3 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Adams et al. (Pat. No. 4,589,420).

The examiner considers claim 3 to be anticipated by virtue of the fact that the amplitude of the peak (defined as a value peak amplitude = $|x(i) - x(i-K)|$ (note for example col. 5, lines 45-55)) must be greater than a first threshold ATOL OVR (note col. 7, lines 55-59) in order for the local maximum or minimum to be counted as noise. In any event, it would have been obvious to any one of ordinary skill in the art to reject turning points from factoring into the determination of noise if said turning points represented relatively small –and thus insignificant—changes in the waveform. Counting all turning points would necessarily make the device overly sensitive and thus taint the outcome of any noise determination.

Claim Rejections - 35 USC § 103

10. Claims 5 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (Pat. No. 4,589,420) in view of Mouchawar et al. (Pat. No. 6,321,115).

Regarding claim 5, Adams et al. do not concern themselves with a discussion of noise flags. The use of flags, however, to signify a “true” condition in logic circuits so as to control device operation is old and well known by those of ordinary skill in the cardiac signal analysis arts. Mouchawar et al., for example, disclose the use of such flags once

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a noise condition is detected in a related cardiac signal analysis method (see Fig. 4A, element 144). Setting a flag in this manner simply notifies the circuit that such a condition was found, and thus allows the circuit program to take appropriate device control steps as a result of this knowledge. Any one of ordinary skill in the art wishing to affect device control based upon sensed noise conditions would have therefore seen the incorporation of such a step as an obvious matter of design dependent upon the function of the system within which the method is employed.

Similar comments apply to claim 12.

11. Claims 9-11, 13-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (Pat. No. 4,589,420).

In regards to claims 9-11, while Adams et al. do not explicitly refer to how many predetermined periodic samples the previous sample and subsequent sample are away from the evaluation sample (i.e., the value of K), those of ordinary skill in the art would have seen the exact number to be a matter of obvious design best established from a study of the application at hand. A relatively high frequency noise component, for example, might require closely spaced sample points (e.g., $K=1$ as worded in claim 11) in order to more accurately account for jittery behavior that might go undetected if the sample points were spaced far apart such as with a high value of K . To make the K values equal would be obvious from a programming standpoint since it simplifies the code and since it is intuitive to center the sample about the suspected turning point. To vary the K value over a range would be obvious as argued above to account for high or low frequency noise with respect to the sampling period.

Regarding claim 13, Adams et al. do not explicitly refer to use of the recited equation for TP in which a TP value of -1 indicates a turning point at $x(i)$. As stated above, however, Adams et al. do teach that a change in sign between two successive first differences is indicative of a local maximum or minimum (col. 6, lines 64-67). Obviously since by definition the sign of a slope for a first segment can be calculated as $x(i)-x(i-K)$ (i.e., the rise) where $x(i)$ is a sample point on a curve and $x(i-K)$ is the sample point along the curve prior to the point $x(i)$, and since the slope sign of a second segment can be by definition calculated as $x(i+K)-x(i)$, where $x(i+K)$ is a sample point on

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the curve subsequent to point $x(i)$, any change in slope (i.e., change in sign) would result in a negative value if the two slope values were to be multiplied together.

Concerning claim 14, note the comments made in the rejection of claim 3 above.

Regarding claim 15, Adams et al. teach that a search for slope sign can be made by taking two successive first differences (bottom of col. 6). This would imply that the sample points are successive with no skipping of points in between. In any event, it would have been considered obvious by those of ordinary skill to calculate a maximum or minimum at an i^{th} sample point by looking at the $i-1$ and $i+1$ points centered about the i^{th} point, in order to get an accurate picture of the slope around the point of interest. Clearly the frequency of the noise influences how close to the i^{th} point one must sample to get meaningful data.

The comment for claim 18 parallels the comment given for related claim 6.

12. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (Pat. No. 4,589,420) as applied to claims above, and further in view of Mouchawar et al. (Pat. No. 6,321,115).

See the rejection of claim 5 above.

13. Claims 13, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maker (Pat. No. 4,960,123) in view of Adams et al. (Pat. No. 4,589,420).

Maker is not concerned with the particular noise detection algorithm used, instead leaving such matters to those of ordinary skill in the art (note col. 4, lines 19-24). Adams et al. disclose a viable noise detection algorithm that can be used to analyze the amount of noise in a cardiac signal (see discussion above on the relevance of the Adams et al. patent to the recited noise detection method). To therefore employ the known noise detection method disclosed by Adams et al. in the device of Maker would have been considered obvious by one of ordinary skill in the art.

Concerning specifically claim 19, Maker teaches that once a noise condition is detected, the gain of the sensing circuitry may be adjusted accordingly (see for example Figs. 3 and 5 and the corresponding text).

Allowable Subject Matter

14. Claims 7 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to disclose the use of both a majority threshold value and a quorum threshold value. The applicants give criticality to this arrangement for the purposes of providing hysteresis (see last paragraph of page 9).

Conclusion


15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cox et al. disclose the detection of inflection points for noise identification (see col. 7).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
June 20, 2004


KENNEDY SCHAETZLE
PRIMARY EXAMINER